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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,914	12/27/2001	Birgit Linhart	0273-0006	6890
7590		12/28/2005	EXAMINER	
Toni-Junell Herbert		HINES, JANA A		
REED SMITH, LLP		ART UNIT		
1301 K Street, N.W.		PAPER NUMBER		
Washington, DC 20005		1645		
DATE MAILED: 12/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,914

Applicant(s)

LINHART ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 13-15, 20-35 is/are pending in the application.
- 4a) Of the above claim(s) 7, 9, 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-15, 20-21, 26-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2005 has been entered.

Amendment Entry

2. The amendment filed September 23, 2005 has been entered. Claims 1-6, 15 and 26 have been amended. Claims 27-35 have been newly added. Claims 7, 9 and 22-25 have been withdrawn. Claims 8, 10-12, 16-19 have been cancelled. Claims 1-6, 13-15, 20-21 and 26-35 are under consideration in this office action.

Withdrawal of Rejections

3. The rejection of claims 1-3, 13-14, 27-28, 30-31 and 33-35 under 35 U.S.C. 103(a) as being unpatentable over Ball et al., (WO 95/34578) in view of Vrtala et al., (1996. J. Allergy Clin. Immun. Vol. 97(3): 781-787) has been withdrawn in view of applicants' amendments. However, it is noted that the rejection may be revived pending ^{resolution of the} the new matter issues.

Response to Arguments

4. Applicant's arguments filed September 23, 2005 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. The written description rejection of claims 13-14, 30-31 and 34-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record. The rejection was on the grounds that the specification and claims lack sufficient written description of a method for preparing a hybrid polypeptide comprising providing a polynucleotide encoding the plant hybrid polypeptide; an introduction step; a culturing step and a recovering step.

Applicants' assert that specific allergen have been isolated and sequenced and that the instant invention teaches and claims a hybrid polypeptide comprising those allergens. However, the instant claims encompass significantly more than just the timothy grass pollen allergens or even a specific allergen. Rather the claims are drawn to a hybrid polypeptide comprising at least two different plant allergens. There is no limitation on which plant allergens nor do the claims only encompass the timothy grass allergens. Thus the claims are significantly broader than applicants' contention. Thus the invention is drawn to absolutely any plant allergens and any modification or fragment, yet there is no written description of such hybrid polypeptides.

Applicants urge that the prior art does not teach hybrid polypeptides of known allergens, and that the instant invention does not concern itself with the detailed

structural profile of the hybrid allergens so long as the functional characteristics claimed to of therapeutic interest is met. However,

“A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representatives, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618. Therefore applicants' arguments are not persuasive.

Furthermore, the claims are not just drawn to the entire polynucleotide and polypeptide sequences, rather the claims encompass fragments thereof wherein each fragment consists of at least eight consecutive amino acids from the respective

allergenic proteins. There is no description of the fragments of nucleic acids that must encode the hybrid polypeptide. The instant specification does not provide for a method for preparing a hybrid polypeptide comprising fragments of polynucleotide. The specification does not provide a teaching of the fragmented structure, showing that nucleic and amino acid fragments were isolated at the time the invention was made, thus there is no teaching of a preparation method. Applicants have failed to address these issues by pointing the support within the specification. Arguments about protective antibodies, or epitope sites fail to address the fact that there is no description of such methods of fragments, thus the rejection is maintained.

Applicants' urged that one of ordinary skill in the art armed with the instant specification, would understand the sequences used in the present invention. However, the standard is not that one would understand the sequences used in the present invention. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. No preparation method has been disclosed. Rather applicants' have disclosed the entire sequences but have failed to disclose a method for preparing a hybrid polypeptide comprising fragments consisting of at least eight consecutive amino acids from the respective allergenic proteins. There is no conception of a method for preparing a hybrid polypeptide comprising fragments thereof as claimed at the time of filing.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is

unquestionable that the claims are broadly generic with respect all possible allergens encompassed by the claims. The possible structural variations are limitless. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient as a characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. Furthermore, applicants have not taught what fragments will encode polynucleotides which are capable of encoding the polypeptide. There is no teaching of a representative fragment polynucleotide encoding a fragment of a polypeptide. There are no in vivo experiments. The specification is limited to the above mentioned timothy grass allergens. The written description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. In view of applicants' failure to explain the essential details the rejection is maintained.

Thus, in the absence of sequence information as claimed applicants arguments, declaration and amendments are not persuasive.

6. The written description rejection of claims 1-6, 13-15, 20-21, 27-29 and 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record. The rejection was on the grounds that there is no written description drawn to a hybrid polypeptide comprising at least two different plant allergenic proteins characterized in that said hybrid polypeptide has reduced allergenic activity compared with the allergenic proteins from which it is derived and which *in vivo* induces protective antibody response, or a hybrid polypeptide comprising at least two different plant allergenic proteins characterized in that at least one of the two different plant allergenic proteins is a fragment thereof consisting of at least eight consecutive amino acids of the respective allergenic protein and which fragment has reduced allergenic activity compared with the allergenic protein from which it is derived and whereby said hybrid polypeptide induces protective antibody response.

Applicants assert that by amending the claims to recite the function of inducing an antibody response the rejection is now moot. However the specification only describes recombinant timothy grass pollen allergens; there is no description of any other type of allergen, nor is there any description of a hybrid polypeptide comprising any other type of plant allergen. Thus, the written description is not commensurate in scope to what is being instantly claimed. Furthermore, applicants have failed to provide any guidance concerning the missing information. Thus, applicants discussion of the

specific timothy grass pollen allergens is not sufficient since the hybrid polypeptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. It is unquestionable that the claims are broadly generic with respect all possible allergens encompassed by the claims. The possible structural variations are limitless, thus a hybrid polypeptide described only by a functional characteristic, fails to meet the written description requirement.

Applicants' assert that because they have provided a generic definition of fragments at pages 2-3 of the instant specification and because the entire sequence is known one of skill in the art would understand that they were in possession. For instance claim 27 fails to teach how to define fragments thereof with respect to which eight consecutive amino acids must be comprised therein to acquire the appropriate fragments. Neither the claims nor the specification teach how to obtain such fragments thereof. There is no guidance as to what amino acids may or may not be included without causing a detrimental effect to the fragments thereof as claimed. The claims broadly recite fragments thereof, therefore any fragment is being claimed, and no specific location requirement for particular amino acids is recited. Thus, the resulting fragments thereof could result in a functional fragment not taught and enabled by the specification. There is no written description of which eight amino acids must be comprised in the claimed hybrid polypeptide. This argument is not persuasive. With the exception of specifically recited sequences the skilled artisan cannot envision the

detailed structure of the fragments thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid and amino acid fragment sequences themselves are required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process as is the case here. Applicants' specification point out fragments can exist, however there is no disclosure of even one representative fragment. Thus one of skill in the art could not immediately envision the claimed fragments. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such

disclosure, easy though it is to imagine it.") (emphasis in original); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion". Similarly, it appears that the instant case sets forth undisclosed fragments and asserts that these undisclosed fragments have some functional limitations. However, there is no actual disclosure of the claimed fragments. Moreover, the functional limitations do not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species.

Applicants assert that they have conveyed with clarity to those skilled in the art that they were possession of the invention. However, at best applicants have shown that they were in possession of the entire sequence of timothy grass allergens, but applicants have not shown that they were in possession of fragments capable of inducing an antibody response. There is no disclosure of a highly conserved and immunogenic region in the plant allergen. Therefore, the specification lacks adequate support for the claims. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of amino acids by only their functional activity, i.e., inducing an antibody response does not provide an adequate description of the genus. The court indicated

that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Currently the instant claims lack an adequate description of the fragments thereof, thus the descriptions are insufficient to support the claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Therefore, the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph and the rejection are maintained.

7. The new matter rejection of claims 1-6, 13-15, 20-21 and 26-35 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

The rejection was on the grounds that neither the specification nor originally presented claims provides support for a hybrid polypeptide comprising at least two different plant allergenic proteins characterized in that said hybrid polypeptide has reduced allergenic activity compared with the allergenic proteins from which it is derived and which *in vivo* induces protective antibody response, or a hybrid polypeptide comprising at least two different plant allergenic proteins characterized in that at least

one of the two different plant allergenic proteins is a fragment thereof consisting of at least eight consecutive amino acids of the respective allergenic protein and which fragment has reduced allergenic activity compared with the allergenic protein from which it is derived and whereby said hybrid polypeptide induces protective antibody response.

Applicant has pointed to pages 2-4, Table 1-2 and Figures 1, 2, 5 and 7 of the instant specification and claims for support of the amendment which are drawn to the hybrid polypeptide comprising at least two different plant allergenic proteins and hybrid polypeptides comprising fragments consisting of at least eight consecutive amino acids of the respective allergenic protein and said hybrid polypeptide induces an antibody response, however it appears that the entire specification appears to fail to recite support for the generically claimed hybrid polypeptides. Applicant has failed to point to a teaching associated with any isolated fragments or these fragments being comprised within a hybrid polypeptide. There is no teaching of a hybrid polypeptide comprising the generic components which induce an *in vivo* protective antibody response in any host. There are no challenge experiments which would show that *in vivo* protection has been achieved. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of such generic hybrid polypeptides as recited by the new and amended claims. Therefore, the claims incorporate new matter and the rejection is maintained since applicants' arguments are not persuasive.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 13-15, 20-21 and 26-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

The claims are drawn to a hybrid polypeptide comprising at least two different plant allergenic proteins characterized in that said hybrid polypeptide has reduced allergenic activity compared with the allergenic proteins from which it is derived and which *in vivo* induces protective antibody response, or a hybrid polypeptide comprising at least two different plant allergenic proteins characterized in that at least one of the two different plant allergenic proteins is a fragment thereof consisting of at least eight consecutive amino acids of the respective allergenic protein and which fragment has reduced allergenic activity compared with the allergenic protein from which it is derived and whereby said hybrid polypeptide induces protective antibody response.

The specification is not enabled for the induction of a protective immune response without a clear teaching of the immunoepitopes that induce a protective immune response; the specification lacks any description of a structure or relevant identifying

characteristics of a representative number of polypeptides sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. One of skill in the art would be reduced to merely randomly including different plant allergenic proteins which would lead to unpredictable results regarding the functional activity of the polypeptide and the ability of the polypeptide to elicit a protective immune response. The art is replete with examples that even one amino acid change can lead to unpredictable changes in the biological activity of the protein.

Moreover, there is no evidence of record of a relationship between the structure of the instantly claimed polypeptide with that of the prior art that would provide any reliable information about the structure of the missing and/or unknown portions of the allergenic proteins. There is no evidence the instantly claimed hybrid polypeptides that will have the ability to *in vivo* induce a protective antibody response. The art indicates that the structure of the polypeptides would be expected to be highly variant. There is no factual evidence that the hybrid polypeptide will produce antibodies and induce a protective immune response, thus this conclusion is not deemed to be reasonably supported in the specification. As to the asserted use, of eliciting an *in vivo* protective immune response, the specification lacks a clear demonstration that the hybrid polypeptide of the instant claims is suitable for immunization. This demonstration is required for the skilled artisan to be able to use the claimed hybrid polypeptides for their intended purpose of inducing an *in vivo* protective immune response. In view of the absence of working examples, the breadth of the claim, and the unpredictable state of the art with respect to inducing a protective antibody response without a clear teaching

of the immunoepitopes that induce a protective immune response, it would require undue experimentation for one skilled in the art to practice the entire scope of the claimed invention.

The ability to reasonably predict the capacity of a single immunogen to induce protective immunity from *in vitro* antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies" (page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an *in vitro* neutralizing antibody response fail to elicit *in vivo* protective immunity. See Boslego et al. wherein a single pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). The specification fails to teach the identity of other hybrid polypeptides with the claimed characteristics, i.e. capable of inducing protective immunity. Accordingly, the art indicates that it would require undue experimentation to formulate and use the hybrid polypeptide without the prior demonstration of efficacy.

This demonstration is required for the skilled artisan to be able to use the claimed hybrid polypeptides for their intended purpose. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed hybrid polypeptides, i.e. would not be able to accurately predict if protective immunity has been induced. The specification fails to teach the identity of the hybrid polypeptide with the claimed ability. Furthermore, the specification fails to adequately disclose a description of the claimed hybrid polypeptides, thus a skilled artisan would be

Art Unit: 1645

required to *de novo* locate, identify and characterize the claimed hybrid polypeptides with the recited abilities. Accordingly, this would require undue experimentation given the fact that the specification is completely lacking in teachings as to hybrid polypeptides with the broadly claimed protection abilities. In absence of further guidance from Applicants, the skilled artisan would have to discover what the appropriate different plant allergenic proteins would be. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of the hybrid polypeptide. Thus, the art indicates that it would require undue experimentation to formulate and use a successful hybrid polypeptides without the prior demonstration of an *in vivo* induced protective antibody response. In the absence of a teaching of the claimed hybrid polypeptide and in view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to use the invention as claimed. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Conclusion


9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
December 6, 2005


ROBERT A. ZEMAN
PATENT EXAMINER